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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,485	04/19/2004	Makarand P. Gore	200315628-1	3286
<div>22879 7590 10/26/2007</div> <div>HEWLETT-PACKARD COMPANY P O BOX 272400, 3404 E. HARMONY ROAD INTELLECTUAL PROPERTY ADMINISTRATION FORT COLLINS, CO 80527-2400</div>				
			<div>EXAMINER</div> <div>HOFFER, SUSANNA MARIE</div>	
			<div>ART UNIT</div> <div>4133</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>10/26/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/827,485		GORE, MAKARAND P.	
	Examiner		Art Unit	
	Susanna Hoffer		4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 19-44 and 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,45 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :15 Sept 2005, 29 April 2004, 19 April 2004.

DETAILED ACTION

Election/Restrictions

Claims 19-44 and 47-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 28, 2007.

Claims 1-18 and 45-46 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 recites the limitation "encapsulated" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-15, 17, and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Backlund et al. (US 6,004,580).

The claims are drawn to a jettable solution comprising an oil, surfactant, aqueous solution and pharmaceutical, wherein the solution forms a microemulsion. The pharmaceutical comprises a water insoluble pharmaceutical. The oil and surfactant form a plurality of micelles in aqueous solution or the aqueous solution and surfactant form a plurality of micelles in the naturally occurring oil, which varies the pharmaceutical release rate of the solution. The aqueous solution comprises water. The solution further comprises an edible solvent comprising salt.

Backlund et al. teach a pharmaceutical composition containing a microemulsion made up of a hydrophilic component, a lipophilic component, a surfactant and a drug (abstract). The drug is dissolved in either the hydrophilic or the lipophilic component of the microemulsion (abstract). Suitable lipophilic components include castor oil and soybean oil (col. 4, lines 62-67). Pharmaceutically acceptable surfactants include lecithins, which are edible surfactants (col. 5, lines 47-53). If the surfactant does not have two hydrocarbon chains like lecithin, a salt and a co-surfactant, such as a short-chain alcohol, must be added (col. 2, lines 9-13). Because a surfactant is a surface tension adjusting agent, claim 15 is also anticipated. Backlund et al. also teach that their o/w microemulsions are suitable carriers for cyclosporin, a water-insoluble immunosuppressant (col. 6, lines 12-17). The microemulsions taught by Backlund et al. can be either the oil-in-water or water-in-oil type (Fig. 1; col. 2, lines 21-36). Such a

composition as the one taught by Backlund et al. would inherently vary the release rate of the pharmaceutical depending on the oil used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backlund et al. (US 6,004,580) in view of Woo (Formulation and physicochemical properties of macro- and microemulsions prepared by interfacial ion-pair formation between, see IDS).

Backlund et al., discussed above, does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Backlund et al. because these naturally occurring fatty acids and amino acids are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore,

determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Backlund et al. (US 6,004,580) in view of Kabalnov (US 6,432,183).

Backlund et al., discussed above, does not teach the viscosity or surface tension of the composition.

Kabalnov teaches that inkjet ink compositions can comprise microemulsions (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the optimal viscosity and surface tension for the composition for use in an inkjet because such properties affect the ability of a composition to be dispensed by an inkjet.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Hoffer whose telephone number is (571)272-9345. The examiner can normally be reached on Monday - Friday, 9:00 a.m.-5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4133

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMH

mpw
MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600